Remarks

Reconsideration of the above-mentioned application in view of this response is respectfully submitted. By the present response, claims 1-7, 9, 10, 12, 13, 15-33, and 35-54 are pending in the present application. Entry of the present amendment is respectfully requested.

Rejections under 35 U.S.C. §103

In the Office Action of March 30, 2007, claims 1, 2, 6, 7, 17, 21, 24, 30, 33, 36, 53, and 54 were rejected by the Examiner under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,728,116 to Rosenman (hereinafter 'Rosenman') in view of U.S. Patent No. 5,964,772 to Bolduc, et al. (hereinafter 'Bolduc'). These rejections are respectfully traversed.

Claim 1 recites an apparatus for attaching a first bone to an adjacent second bone, the second bone being separated from the first bone by a space between the adjacent bones. The apparatus comprises an anchor having a platform for drivingly rotating the anchor and at least two helical spikes for embedding into at least one of the first and second bones upon rotation of the platform. The platform has a first surface that is solid and that extends generally transverse to a longitudinal axis of the anchor. The at least two helical spikes project tangentially from the first surface of said platform and extend around the longitudinal axis.

Rosenman appears to teach a surgical tack 10 having a distally extending spiral member 50 extending down from the bottom surface 40 of the base member 30. The base member 20 has a top surface 30 and bottom surface 40 and side surfaces 25 connecting the top surface 30 and the bottom surface 40. The base member 20 preferably has a circular disk-like shape (Col. 3, lines 46-49 and Figs. 1-4). **That is, the bottom surface 40 does not**

extend generally transverse to a longitudinal axis of the tack 10, as recited in claim 1. The second end surface 30 of the present invention is convex, or otherwise designed to be complimentary to an outer surface 19 of the S1 vertebrae (Application Pg. 16 and Fig. 1). Therefore, the structure of the second surface of the anchor is not merely a matter of design choice. Rosenman does not teach or suggest such a surface.

Furthermore, Rosenman appears to teach that the mechanical characteristics of the materials of construction, e.g., stiffness, will be sufficient to effectively enable the tack 10 to penetrate tissue without deforming (Col. 6, lines 17-20). **However, the 'tissue' Rosenman refers to range from soft muscle, fascia, or fat to hard ligaments and tendons (Col. 6, lines 6-8), not hard surfaces like bone. Thus, Rosenman does not teach or suggest a tip portion of the helical spike which is driven into bone as the platform is rotated, as recited in claim 1**. Additionally, the fact that the spike 50 of Rosenman terminates prior to the head 1 of the tack 10 renders the tacks mechanically insufficient for placement into hard surfaces (i.e. bone). Conversely, the helical spikes 50 and 52 of the present invention project from the end surface 38 of the platform 40 and ensure structural integrity during implantation into hard surfaces.

Bolduc does not cure the deficiencies of Rosenman as Bolduc does not appear to teach or suggest a platform having a surface extending generally transverse to a longitudinal axis of the fastener. Bolduc appears to teach that fastener 110 is formed into a double helix configuration (Figs. 2-2C). The proximal end 118 and distal end 120 of the double helical fastener 110 comprise structure to drive the fastener into tissue as well as tissue piercing structures. The proximal end 118 has a connector bar 122 sectioning the diameter of the fastener that connects one helical coil to another (Col. 7, lines 43-48 and Figs. 2A & 2C).

That is, connector bar 122 does not have a surface that extends generally transverse to the longitudinal axis of the fastener 110, as recited in claim 1.

Furthermore, helical fastener 10 (or double helical fastener 110) is attached to tissue by an applicator 12 which rotates fastener 10 into the tissue (Col. 6, lines 12-16 and Fig. 1). As the fastener 10 is pressed against tissue 25, all the coils substantially collapse except the most distal coil 27, leaving gap 23 to determine the path the fastener 10 takes as it is rotated into tissue 25 and the extent of penetration 29 into the tissue 25 (Col. 6, lines 50-55 and Figs. 1B-1E). The fastener 10 is used in such medical procedures as ligating tissue, hernia mesh repair, bladder neck suspension, or otherwise positioning surgical or implantable devices in the patient's body (Col. 2, lines 45-52). **The fastener 10 is simply not structurally sound enough, nor designed for, implantation into bone, as the present invention is**. The fact that fastener 10 is almost fully collapsable, and inserted into tissue 25 simply by manipulating lever 54 to drive nut driver 62 along lead screw 64 (Col. 9, lines 46-60 and Fig. 5) suggests that both the fastener 10 and applicator 12 are incapable of use in bone. Since Bolduc does not cure the deficiencies of Rosenman, it is respectfully submitted that the combination of Rosenman and Bolduc does not teach or suggest the subject matter of claim 1, and thus claim 1 is allowable.

Claims 2, 6, 7, and 17 depend from claim 1 and are allowable for at least the same reasons claim 1 is allowable, and for the specific limitations recited in each claim.

Claim 21 recites an apparatus for attaching a fifth lumbar (L5) vertebrae to a sacrum, the apparatus comprising an anchor for extending between the L5 vertebrae and the sacrum and for attaching the L5 vertebrae to the sacrum. The anchor has a platform for drivingly rotating the anchor. The platform includes a first surface that is solid and that extends

generally transverse to a longitudinal axis of the anchor. The anchor further has at least two helical spikes for embedding into both of the L5 vertebrae and the sacrum upon rotation of the platform, the at least two helical spikes projecting tangentially from the first surface of the platform and extending around the longitudinal axis. The at least two helical spikes have a tip portion at a distal end for penetrating into at least one of the L5 vertebrae and the sacrum as the platform is rotated. The anchor has a first condition in which the at least two helical spikes are embeddable into one of the L5 vertebrae and the sacrum. The anchor further has a second condition in which the at least two helical spikes are embeddable into both of the L5 vertebrae and the sacrum to attach the L5 vertebrae and the sacrum to one another while maintaining an intervertebral space between the L5 vertebrae and the sacrum. The anchor is movable from the first condition to the second condition by rotation of the platform. A portion of each of the at least two helical spikes of the anchor, when the anchor is embedded into the L5 vertebrae and the sacrum, extends across the intervertebral space between the L5 vertebrae and the sacrum.

Rosenman appears to teach a surgical tack 10 having a distally extending spiral member 50 extending down from the bottom surface 40 of the base member 30. The base member 20 has a top surface 30 and bottom surface 40 and side surfaces 25 connecting the top surface 30 and the bottom surface 40. The base member 20 preferably has a circular disk-like shape (Col. 3, lines 46-49 and Figs. 1-4). **That is, the bottom surface 40 does not extend generally transverse to a longitudinal axis of the tack 10, as recited in claim 21**. The second end surface 30 of the present invention is convex, or otherwise designed to be complimentary to an outer surface 19 of the S1 vertebrae (Application Pg. 16 and Fig. 1).

Therefore, the structure of the second surface of the anchor is not merely a matter of design choice. Rosenman does not teach or suggest such a surface.

Furthermore, Rosenman appears to teach that the mechanical characteristics of the materials of construction, e.g., stiffness, will be sufficient to effectively enable the tack 10 to penetrate tissue without deforming (Col. 6, lines 17-20). **However, the 'tissue' Rosenman refers to range from soft muscle, fascia, or fat to hard ligaments and tendons (Col. 6, lines 6-8), not hard surfaces like bone. Thus, Rosenman does not teach or suggest a tip portion of the helical spike which is driven into bone as the platform is rotated, as recited in claim 21**. Additionally, the fact that the spike 50 of Rosenman terminates prior to the head 1 of the tack 10 renders the tacks mechanically insufficient for placement into hard surfaces (i.e. bone). Conversely, the helical spikes 50 and 52 of the present invention project from the end surface 38 of the platform 40 and ensure structural integrity during implantation into hard surfaces.

Bolduc does not cure the deficiencies of Rosenman, as Bolduc does not appear to teach or suggest a platform having a surface extending generally transverse to a longitudinal axis of the fastener. Bolduc appears to teach that fastener 110 is formed into a double helix configuration (Figs. 2-2C). The proximal end 118 and distal end 120 of the double helical fastener 110 comprise structure to drive the fastener into tissue as well as tissue piercing structures. The proximal end 118 has a connector bar 122 sectioning the diameter of the fastener that connects one helical coil to another (Col. 7, lines 43-48 and Figs. 2A & 2C). **That is, connector bar 122 does not have a surface that extends generally transverse to the longitudinal axis of the fastener 110, as recited in claim 21.**

Furthermore, helical fastener 10 (or double helical fastener 110) is attached to tissue by an applicator 12 which rotates fastener 10 into the tissue (Col. 6, lines 12-16 and Fig. 1). As the fastener 10 is pressed against tissue 25, all the coils substantially collapse except the most distal coil 27, leaving gap 23 to determine the path the fastener 10 takes as it is rotated into tissue 25 and the extent of penetration 29 into the tissue 25 (Col. 6, lines 50-55 and Figs. 1B-1E). The fastener 10 is used in such medical procedures as ligating tissue, hernia mesh repair, bladder neck suspension, or otherwise positioning surgical or implantable devices in the patient's body (Col. 2, lines 45-52). **The fastener 10 is simply not structurally sound enough, nor designed for, implantation into bone, as the present invention is**. The fact that fastener 10 is almost fully collapsable, and inserted into tissue 25 simply by manipulating lever 54 to drive nut driver 62 along lead screw 64 (Col. 9, lines 46-60 and Fig. 5) suggests that both the fastener 10 and applicator 12 are incapable of use in bone. Since Bolduc does not cure the deficiencies of Rosenman, it is respectfully submitted that the combination of Rosenman and Bolduc does not teach or suggest the subject matter of claim 21, and thus claim 21 is allowable.

Claims 30, 33, and 36 depend from claim 21 and are allowable for at least the same reasons claim 21 is allowable, and for the specific limitations recited in each claim.

Claim 24 recites that when the anchor is in the second condition, at least a portion of the platform is recessed into an anterior surface of the sacrum. Rosenman does not teach or suggest that a portion of the base member 20 is recessed into any of the 'soft' tissues mentioned above. The surgical tack 10 of Rosenman is designed to approximate tissues, to hold a medical device to the surface of tissue including, for example, a surgical mesh, or to anchor tissue to an anatomic site (Col. 5, lines 41-44). **Since the base member 20 has a**

larger footprint then the distally extending member 50 (Figs. 3 and 12-15), no amount of rotation of the tack 10 into the soft tissue will result in the base member 20 being recessed into the anterior surface of the soft tissue. Furthermore, soft tissue cannot be pre-conditioned like hard tissue can to receive the head of the tack (i.e. drilled or countersunk).

Bolduc does not cure the deficiencies of Rosenman. As noted, the helical fastener 10 in Bolduc is not suitable for implantation into bone, such as the sacrum. **That is, no portion of connector 118 is capable of being recessed into bone, such as the sacrum**. Since Bolduc does not cure the deficiencies of Rosenman, it is respectfully submitted that the combination of Rosenman and Bolduc does not teach or suggest the subject matter of claim 24, and thus claim 24 is allowable.

Claim 53 recites an apparatus for attaching a first bone to an adjacent second bone. The second bone is separated from the first bone by a space between the adjacent bones. The apparatus comprises an anchor having a platform for drivingly rotating the anchor and at least two helical spikes for embedding into at least one of the first and second bones. Upon rotation of the platform, the platform has a first surface that extends generally transverse to a longitudinal axis of the anchor. At least two helical spikes project from the first surface of the platform and extend around the longitudinal axis. The at least two helical spikes have a tip portion at a distal end which penetrates into bone as the platform is rotated. The anchor has a first condition in which a first portion of each of the at least two helical spikes is extendable into one of the first and second bones. The anchor further having a second condition in which the first portions are extendable into the other of the first and second bones and a second portion of each of said at least two helical spikes is extendable into the one bone to attach the first and second bones to one another while maintaining the space between the

bones. Each of the at least two helical spikes further includes a third portion extending between the first and second portions and that, when the anchor is embedded into the first and second bones, extends across the space between the bones, wherein one of the first and second bones is the sacrum and the other of said first and second bones is the fifth lumbar (L5) vertebrae.

Rosenman appears to teach a surgical tack 10 having a distally extending spiral member 50 extending down from the bottom surface 40 of the base member 30. The base member 20 has a top surface 30 and bottom surface 40 and side surfaces 25 connecting the top surface 30 and the bottom surface 40. The base member 20 preferably has a circular disk-like shape (Col. 3, lines 46-49 and Figs. 1-4). **<u>That is, the bottom surface 40 does not extend generally transverse to a longitudinal axis of the tack 10, as recited in claim 53</u>**. The second end surface 30 of the present invention is convex, or otherwise designed to be complimentary to an outer surface 19 of the S1 vertebrae (Application Pg. 16 and Fig. 1). Therefore, the structure of the second surface of the anchor is not merely a matter of design choice. Rosenman does not teach or suggest such a surface.

Furthermore, Rosenman appears to teach that the mechanical characteristics of the materials of construction, e.g., stiffness, will be sufficient to effectively enable the tack 10 to penetrate tissue without deforming (Col. 6, lines 17-20). **<u>However, the 'tissue' Rosenman refers to range from soft muscle, fascia, or fat to hard ligaments and tendons (Col. 6, lines 6-8), not hard surfaces like bone. Thus, Rosenman does not teach or suggest a tip portion of the helical spike which is driven into bone as the platform is rotated, as recited in claim 53</u>**. Additionally, the fact that the spike 50 of Rosenman terminates prior to the head 1 of the tack 10 renders the tacks mechanically insufficient for placement into hard

surfaces (i.e. bone). Conversely, the helical spikes 50 and 52 of the present invention project from the end surface 38 of the platform 40 and ensure structural integrity during implantation into hard surfaces.

Bolduc does not cure the deficiencies of Rosenman as Bolduc does not appear to teach or suggest a platform having a surface extending generally transverse to a longitudinal axis of the fastener. Bolduc appears to teach that fastener 110 is formed into a double helix configuration (Figs. 2-2C). The proximal end 118 and distal end 120 of the double helical fastener 110 comprise structure to drive the fastener into tissue as well as tissue piercing structures. The proximal end 118 has a connector bar 122 sectioning the diameter of the fastener that connects one helical coil to another (Col. 7, lines 43-48 and Figs. 2A & 2C). **That is, connector bar 122 does not have a surface that extends generally transverse to the longitudinal axis of the fastener 110, as recited in claim 53.**

Furthermore, helical fastener 10 (or double helical fastener 110) is attached to tissue by an applicator 12 which rotates fastener 10 into the tissue (Col. 6, lines 12-16 and Fig. 1). As the fastener 10 is pressed against tissue 25, all the coils substantially collapse except the most distal coil 27, leaving gap 23 to determine the path the fastener 10 takes as it is rotated into tissue 25 and the extent of penetration 29 into the tissue 25 (Col. 6, lines 50-55 and Figs. 1B-1E). The fastener 10 is used in such medical procedures as ligating tissue, hernia mesh repair, bladder neck suspension, or otherwise positioning surgical or implantable devices in the patient's body (Col. 2, lines 45-52). **The fastener 10 is simply not structurally sound enough, nor designed for, implantation into bone, as the present invention is**. The fact that fastener 10 is almost fully collapsable, and inserted into tissue 25 simply by manipulating lever 54 to drive nut driver 62 along lead screw 64 (Col. 9,

lines 46-60 and Fig. 5) suggests that both the fastener 10 and applicator 12 are incapable of use in bone. Since Bolduc does not cure the deficiencies of Rosenman, it is respectfully submitted that the combination of Rosenman and Bolduc does not teach or suggest the subject matter of claim 53, and thus claim 53 is allowable.

Claim 54 recites that when the anchor is in the second condition, at least a portion of the platform is recessed into an outer surface of one of the sacrum or the L5 vertebrae. Rosenman does not teach or suggest that a portion of the base member 20 is recessed into any of the 'soft' tissues mentioned above. The surgical tack 10 of Rosenman is designed to approximate tissues, to hold a medical device to the surface of tissue including, for example, a surgical mesh, or to anchor tissue to an anatomic site (Col. 5, lines 41-44). **Since the base member 20 has a larger footprint then the distally extending member 50 (Figs. 3 and 12-15), no amount of rotation of the tack 10 into the soft tissue will result in the base member 20 being recessed into the anterior surface of the soft tissue**. Furthermore, soft tissue cannot be pre-conditioned like hard tissue can to receive the head of the tack (i.e. drilled or countersunk).

Bolduc does not cure the deficiencies of Rosenman. As noted, the helical fastener 10 in Bolduc is not suitable for implantation into bone, such as the sacrum. **That is, no portion of connector 118 is capable of being recessed into bone, such as the sacrum or L5 vertebrae**. Since Bolduc does not cure the deficiencies of Rosenman, it is respectfully submitted that the combination of Rosenman and Bolduc does not teach or suggest the subject matter of claim 54, and thus claim 54 is allowable.

In view of the foregoing, it is respectfully requested that the above-identified amendment be entered and the application allowed.

Please charge any deficiency or credit any overpayment in the fees for this amendment to our Deposit Account No. 20-0090.

Respectfully submitted,

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